

REMARKS

I. Status of Claims.

Claims 1-11 are presently pending. Claims 1-11 stand rejected.

II. Amendment to the claims.

Claims 6 and 7, 10 and 11 have been amended. Support for amendments to claims 7, 10 and 11 can be found generally throughout the application with particular reference to paragraph 41. Support for the amendment to claim 6 can be found generally throughout the application. No new matter is believed to be introduced by these amendments.

III. Interview.

An interview concerning the instant application was conducted on March 26, 2003 with Examiner Meller of the United States Patent Office and Applicants' attorney John C. Serio. Applicants thank Examiner Meller for courtesies extended in the granting and conducting of the interview. The Examiner suggested, during the interview, that 35 USC 112 rejections may be addressed by providing a reference that more clearly defines the use of the word effectors. Applicants subsequently provided Examiner Meller with a text book chapter concerning the word "effectors" as used by those skilled in the art.

Applicants had a supplemental interview with the Examiner related to the submitted reference. During the supplemental interview no agreement was reached regarding the use of the word effectors, however, the Examiner indicated that he would further consider Applicants' claimed subject matter in light of the submitted reference. Applicants thank the Examiner for the opportunity to discuss the pending application.

IV. Rejection of claims 7-11 under 35 USC 112, first paragraph.

In the Office Action dated January 27, 2003 the Examiner rejected newly added claims 7-11 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner stated that the phrase, “a compound having a means for modulating enzymatic activity of DPIV and DPIV analogous enzymes’ is not supported by the instant specification.

Applicants have amended claims 7, 10 and 11 to more clearly define and emphasize their invention. In the instant specification the influencing of enzymatic activity of DPIV and DPIV analogous enzymes finds clear support within the instant application. Specifically, paragraph 39 of the specification provides that “by influencing DP IV activity and analogous activities; simultaneous stimulation of glucose degradation does not occur...” Claim 7 and its dependent claims as amended clearly define Applicants’ invention. Applicants respectfully request that this rejection be withdrawn.

The Examiner further rejected claims 1-11 under 35 USC 112, first paragraph because the specification, while being enabling for a method of administering to a mammal a therapeutically effective amount of an inhibitor of DPIV does not reasonably provide enablement for administering any and all effectors for reducing enzymatic activity of DPIV and DPIV analogous enzymes. Applicants respectfully traverse this rejection.

The use of the word effectors is described within the specification to express an activity upon DP IV and DP IV analogous enzymatic activity that is not restricted to the inhibition of

enzymatic activity but more clearly that of an effect upon these enzymes that results in the influence of their activity. In particular, in paragraph 47 of the instant specification the effectors are described not only as inhibitors, but also “substrates, pseudosubstrates, inhibitors of DP IV expression, binding proteins or antibodies to those enzyme proteins or combinations of those different substances that reduce the DP IV or DP IV analogous protein concentration in the mammalian organism.” (Applicants’ specification paragraph 47). Applicants’ specification sets forth other methods that can influence the activity of enzymatic activity of DPIV. Applicants would respectfully request that this rejection be withdrawn.

V. Rejection of claims 1-5 and 7-11 under 35 USC 112, second paragraph.

The Examiner further rejected claims 1-5 and 7-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner objected to the phrase “an effector for reducing enzymatic activity of DPIV and DPIV analogous enzymes” as being confusing and therefore failing to clearly point out Applicants’ invention. Applicants respectfully traverse the rejection of claims 1-5 under section 112 second paragraph.

Applicants have attached to this response a chapter from a textbook well known in the art, which was submitted to the Examiner during the course of the above noted telephonic interview. It is clear that the word “effector” is a term known in the art that describes molecules that bind to enzymes that can either increase or decrease their activities. (Molecular Cell Biology 2nd Edition, Darnell, Lodish and Baltimore page 63).

Within the specification the word "effectors" is used in at least paragraphs 2, 12, 13, 43, 44, 47 and 50. Therein "effectors" describe the reduction of DP IV and DP IV analogous enzymatic activity. Nowhere is it required that the reduction be complete inhibition of enzymatic activity but rather, reduction may be something less than complete inhibition.

For example, paragraph 47 of the instant specification describes effectors not only as inhibitors, but also as "substrates, pseudo substrates, inhibitors of DP IV expression, binding proteins or antibodies to those enzyme proteins or combinations of those different substances that reduce." It is respectfully submitted that the term "effectors" is one that is well known and understood by those skilled in the art. Applicants have clearly defined their claim invention under the provision of 35 USC 112, second paragraph and respectfully request that the rejection of claims 1-5 be withdrawn.

The Examiner further rejected claims 7-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner states that the phrase "a compound having a means for modulating enzymatic activity of DP IV and DP IV analogous enzymes" is confusing and asks how one modulates activity. Applicants reiterate their response as to paragraph one rejections above and in addition, have amended the claims to replace "modulating" with "influencing".

The enzymatic activity of DP IV and DP IV analogous enzymes can be "influenced" by a variety of mechanisms. These mechanisms include but are not limited to directly inhibiting the activity of DP IV or DP IV analogous enzymes or indirectly by providing a substrate or pseudo-

CONCLUSION

For the foregoing reasons and with the above requested amendments, Applicants believe this application is in condition for allowance which is respectfully requested.

Respectfully submitted,



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